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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433
23557 7590 06/29/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/636,079

Applicant(s)

YAMAMOTO, JANET K.

Examiner

Stacy B. Chen

Art Unit

1648

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 25 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: 32, 53, 54, 63 and 109-119.  
Claim(s) rejected: 31, 35, 36, 50, 55-58, 108, 120 and 121.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

## Continuation of Item 5.

Applicant's reply has overcome the following rejection(s): The rejection of claims 33, 34, 59-62 and 109 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is withdrawn in view of Applicant's amendment.

## Continuation of Item 7.

Applicant's amendment filed May 25, 2007 is acknowledged and entered. Claims 31, 32, 35, 36, 50, 53-58, 63 and 108-121 are pending and under examination.

Claims 31, 34, 36, 50, 55-58, 108, 120 and 121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine composition that induces a protective immune response against two or more subtypes of FIV, comprising an effective amount of an FIV immunogen that minimally includes the FIV envelope glycoprotein, does not reasonably provide enablement for a vaccine comprising FIV peptides, proteins, and partial viruses that do not include the FIV envelope glycoprotein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims broadly encompass a vaccine composition that induces protection against FIV infection (of multiple subtypes), comprising an amount of any FIV immunogen. The immunogens include synthetic FIV peptides, natural or recombinant FIV proteins, fragments of said proteins, cell-free whole or partial FIV virus, and cells infected with FIV virus. Applicant's specification is enabling for embodiments that encompass the FIV envelope glycoprotein from each of the at least two different FIV subtypes. Embodiments that do not encompass the envelope glycoprotein from each of the at least two different subtypes, are not enabled by the specification.

Applicant's arguments have been carefully considered but found unpersuasive. Applicant asserts the Coleman et al. publication (2005) teaches the use of FIV immunogens, including FIV p24 protein (pages 1458-1460, including Table 1 and 2, study groups 2-2 and 2-3). In response to Applicant's assertion, the Office has considered the Coleman et al. reference again, and found that FIV p24 was administered to cats as asserted by Applicant. Table 1 shows that the cats were challenged with FIV subtype A in combination with Ribi/rHuIL-12, and protected against subtype A. Therefore, there are other immunogens from FIV that are capable of inducing a protective immune response against subtype A challenge when administered with an appropriate adjuvant. However, the instant claims require that the composition be capable of inducing a protective immune response against two or more subtypes without adjuvant, or with adjuvants that are not demonstrated as capable of enhancing the immune response to the degree of protection against FIV challenge. This has not been demonstrated in the specification or in Coleman et al.

With regard to Applicant's assertion that the patents submitted with the amendment dated September 26, 2006 are relevant to the enablement issues raised by the Office, Applicant maintains their position that combinations of env and gag, and gag and pro, have been shown to be protective. Applicant asserts that all of the publications previously submitted show that the use of FIV immunogens other than FIV envelope protein can induce an immunogenic response. Applicant asserts that the Examiner is incorporating a limitation ("protein vaccines") that is not present in Applicant's claims, because most of the claims are not limited to protein vaccines. Applicant asserts that they have provided evidence directly relevant to protein-based vaccines. In response to Applicant's assertions, the claims encompass protein-based vaccines, which the Office referred to as "protein vaccines". The embodiments in the claims, where specified, are protein-based vaccines. The immune response to gene products is not analogous art to the instant invention as a whole. While an "immunogen" may encompass gene products, the instant specification does not appear to have contemplated such embodiments. Thus, the art relating to the protective capabilities of non-env embodiments is not relevant to the instant protein-based constructs.

/Stacy B. Chen/ 6-25-2007  
Primary Examiner, TC1600